CLINICAL RESEARCH STUDIES

Endovascular repair of aortoiliac aneurysmal disease with the helical iliac bifurcation device and the bifurcated-bifurcated iliac bifurcation device

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Background: **Iliac branch device (IBD) treatment of common and internal iliac artery (CIA and IIA) aneurysms has been controversial in the context of available embolization techniques or off-label adjunctive procedures. Two devices exist, a straight IBD (S-IBD) and a helical IBD (H-IBD). We report our midterm results with the latter and present outcomes with a third device intended to treat disease in the presence of short CIAs termed the bifurcated-bifurcated IBD (BB-IBD).**

Methods: **Data were prospectively collected from IBD-treated patients with infrarenal aortoiliac or thoracoabdominal aortoiliac aneurysms. Preoperative aneurysmal characteristics were collected in accordance with the endovascular reporting standards document, including presence of IIA stenosis, CIA diameters, and the presence of an IIA aneurysm. Technical success was defined as IBD device placement, branch placement, and patency without type I or III endoleak at implantation in addition to 24 hours survival. Follow-up computed tomography scans at 1, 6 (optional), 12 months, and annually thereafter were performed and reinterventions, sac morphology changes, and endoleaks noted. Survival and patency were evaluated with life-table analyses, and differences among anatomic groups were compared with log-rank tests, whereas *t*-tests and Fisher exact tests were used to compare simple variables.**

Results: **Between 2003 and 2012, 138 IBD devices were placed into 130 patients (98 H-IBD and 40 BB-IBD). Median follow-up was 20.3 months (range, 1-72 months) with 30- day, 12-month, 3- and 5-year survival rates of 99%, 90%, 79%, and 62%, respectively. Technical success was 94%, and branch patency was 94.6% at 30 days and 81.8% at 5 years. Thirty-five percent (35%) of branches were placed into patients with IIA aneurysms (in addition to their proximal disease), 20% into stenotic IIAs, and 46% into iliac systems with narrow (<16 mm) CIAs. Technical success was significantly lower in patients with IIA stenosis (81.5 vs 96.4%; Fisher exact test, $P = .015$) but not affected by the presence of an IIA aneurysm or narrow CIA. Branch patency was similar in all groups throughout follow-up. No stent fractures or component separations were noted in the IBDs or mating devices throughout the study period.**

Conclusions: **The H-IBD and BB-IBD configurations have high technical success and acceptable long-term patency for the treatment of CIA and IIA aneurysms, including those with challenging anatomy difficult to treat with the straight branch design. (J Vasc Surg 2013;58:861-9.)**

In aortoiliac aneurysm repair, preservation of hypogastric blood flow has an important role in preventing buttock claudication as well as less common complications including ischemic colitis, gluteal necrosis, spinal cord ischemia, and sexual dysfunction. Endovascular techniques such as the bell bottom,[1] snorkel,[2] or extra-anatomic bypass procedures[3,4] have been employed to preserve antegrade internal iliac artery (IIA) flow. Yet, all of these methods have the potential for persistent pressurization of diseased common iliac arteries (CIAs) and lack appropriate preclinical testing or manufacturer backing. Branched device treatment of CIA/IIA aneurysms has been described, but large series with long-term follow-up are scarce.[5,6] Two device versions (Fig 1), a straight branch-iliac branch device (S-IBD) and helical branch-iliac branch device (H-IBD), both by Cook Inc (Bloomington, Ind), are commercially available outside the United States, while both devices are undergoing clinical trials in the United States. Technical differences include the length of overlap with the mating internal iliac stent grafts, the mechanism of directing flow into the branch, and (historically) the use of self-expanding rather than balloon-expandable stent grafts within the IIA. Both devices are unable to handle short CIAs without the addition of two or more modular joints within the aneurysm sac, potentially

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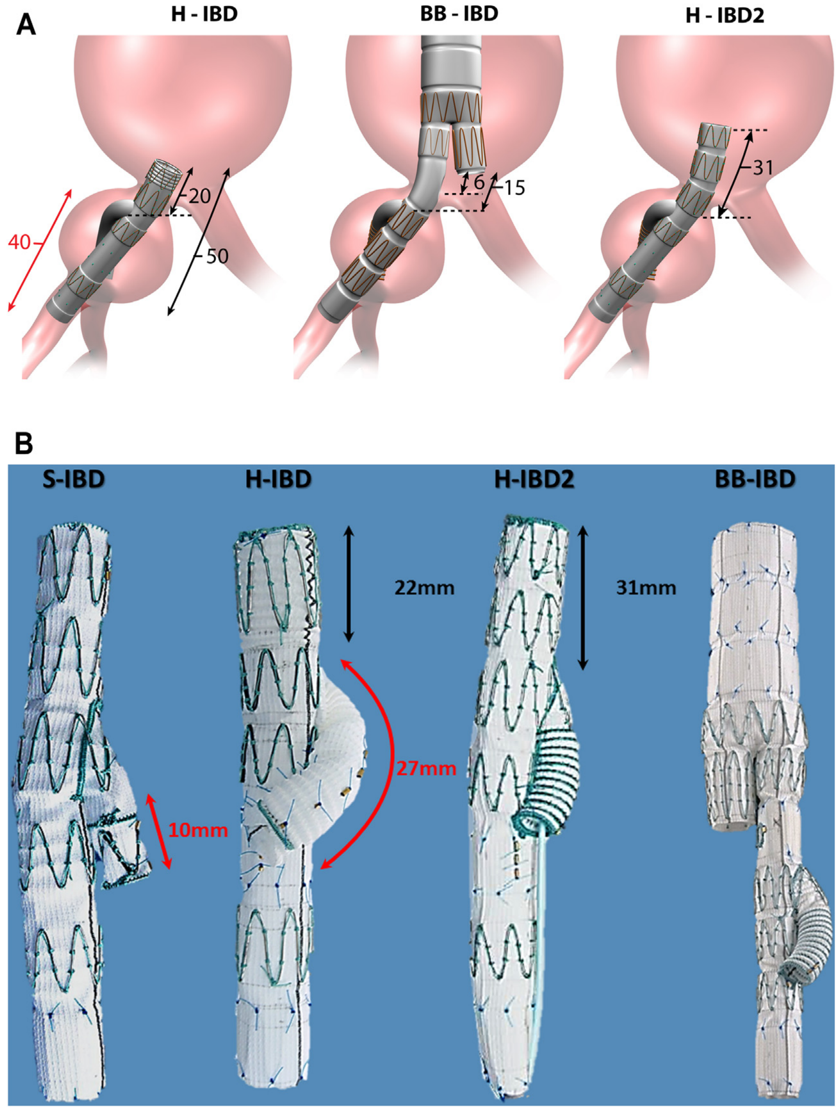

Fig 1. A, This figure demonstrates the differences between the three devices. The helical iliac branch device (*H-IBD*) is about 5 cm long and, thus, extends 1 cm into the aortic portion on an abdominal aortic aneurysm if the common iliac artery (CIA) is slightly longer than 4 cm, placing two modular joints within a potentially large volume. If the CIA is shorter, then the device is even higher potentially compromising durability more and making the procedure much more challenging. The bifurcated-bifurcated IBD (*BB-IBD*) is designed for shorter CIAs, by allowing for the treatment of aneurysms involving CIAs as short as 2 to 2.5 cm without difficulty. Longer CIA aneurysms can also be treated, but the mating device to reach the internal iliac artery (IIA) landing zone must then be longer as well. Once the BB-IBD was developed, the need to treat CIAs that were shorter than 5.5 to 6 cm was obliviated, so the H-IBD2 was developed by lengthening the overlap with the aortic component to add more security to the joint. **B,** These images represent the actual devices. The straight IBD (*S-IBD*) is depicted first; note the minimal (10-15 mm) overlap zone in contrast to the H-IBD where the wrap of the branch around the device extends the overlap zone to 27 mm. The H-IBD2 has the extended overlap zone with the mating component increasing it from 22 mm in the H-IBD1 to 31 mm in the H-IBD2. The BB-IBD is designed to mate with a 24-mm-diameter tubular graft in the distal aorta. This is identical to the distal components used in fenestrated and branched grafts, making this an ideal distal component for such cases, replacing the distal bifurcated component that would have to be combined with an IBD to achieve treatment of a CIA or IIA aneurysm.

destabilizing the more proximal aortic repair. To address this issue, a third device, termed the bifurcated-bifurcated iliac branch device (BB-IBD) was developed. This device incorporates a helical IBD into the ipsilateral leg of an aortic bifurcated graft. This article describes our experience with the H-IBD and BB-IBD.

METHODS

Two physician-sponsored investigational device exemption trials, one for infrarenal abdominal aortic aneurysms (NIH study #5834141) and one for thoracoabdominal aortic aneurysms (TAAAs: #583050), incorporated the use of IBD beginning in 2003 for patients with concomitant CIA and/or IIA aneurysms. All patients were considered high risk for surgical repair and signed informed consent approved by our Institutional Review Board. Inclusion, exclusion, and other trial details have been previously described,[7,8] with those specific to the IBD detailed below. Patients were evaluated with preoperative high-resolution computed tomography, which was postprocessed using a three-dimensional workstation (Aquarius Intuition; Terarecon, Santa Rosa Calif). Patients with CIA aneurysmal involvement were considered for treatment with an IBD based on the following specific criteria: (1) an IIA circulation distal fixation site (main trunk or divisional branch) ≤10 mm diameter and ≥10 mm length; (2) iliac vasculature not precluding delivery or device orientation (extreme angulation or calcific stenosis); and (3) activity level that would be significantly altered by claudication or, a significant risk of spinal cord ischemia with TAAA repair.

Following BB-IBD availability in June 2008, patients with CIAs <5.5 cm in length were preferentially treated with this device, whereas CIAs >6 cm in length were treated with an H-IBD (Fig 1, *A*). Device choice in patients with CIAs 5.5 to 6 cm in length was left to the discretion of the treating physician. After BB-IBD availability, the H-IBD was no longer needed to treat shorter CIAs and was therefore modified with the addition of a single stent proximally, designed to increase its overlap with any mating aortic device (H-IBD2; Fig 1). In addition, nitinol rings were added to the helical branch on both devices to further reinforce the branch. Patients treated for bilateral disease received either two H-IBDs or a BB-IBD and one H-IBD, the latter being implanted on the side with the longer CIA.

Device descriptions: H-IBD. This device closely resembles a conventional limb extension with a 27-mm-long side arm (crimped fabric tube) anastomosed 22 mm distal to its proximal edge in an end-to-side fashion (31 mm in the H-IBD2; Fig 1, *B*). This branch travels in a helical path (180°) around the external posterior portion of the iliac leg providing an extensive overlap zone with mating devices while orienting the terminal branch ostium in the line with the natural direction of IIA flow. This helps minimize any angulation within any mating stent graft device to optimize flow dynamics, minimize distraction forces, and decrease risks of stent fracture (Fig 2). Prior to 2005, two diameters (6 and 8 mm) were available for the helical branch; after 2005, 8-mm branches were used for all patients. A left-oriented and a right-oriented device exist and are used in the corresponding CIAs resulting in the distal branch ostium directed toward the posteromedial aspect of the distal CIA, preferably in close proximity to the IIA ostium. All common and external iliac components are 12 mm in diameter, while the overall device length proximal to the branch terminus is 54 mm (prior to BB-IBD introduction; 63 mm with the H-IBD2). All devices extend 52 mm distal to the branch terminus to seal within the external iliac artery (EIA) with a terminal diameter of 12 mm.

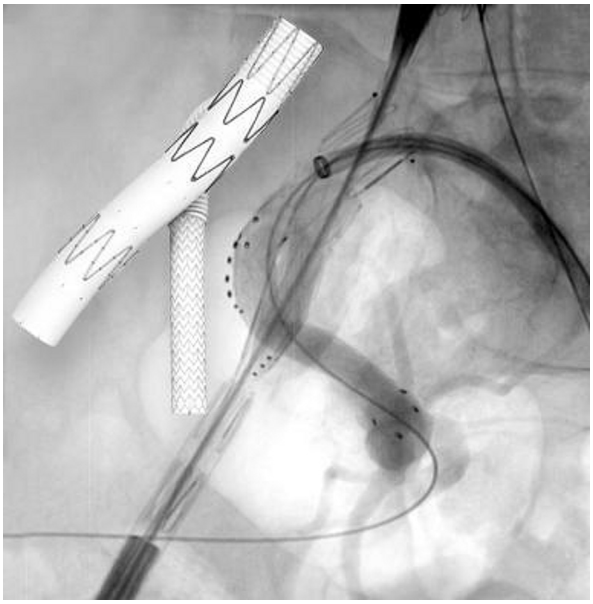

Fig 2. This image superimposes a completed iliac branch device (IBD) with the underlying angiogram depicting the relationship between the natural lay of the mating Fluency stent graft with the intended treatment anatomy.

The H-IBD is loaded into a 20F sheath and has a preloaded wire and catheter passing external to the distal portion of the implant, entering the distal helical branch ostium and passing through the common iliac segment exiting the sheath along a grooved pusher device. By snaring this wire from an alternative access site (contralateral groin or upper extremity), through-and-through access is established. A sheath (10-12F) is inserted over the through-and-through wire directly into the helical branch, through which a steerable catheter-guidewire combination is used to establish access deep into the IIA circulation (preferably within the posterior branch). The mating device (Fluency 10-mm diameter, 6-8 cm in length; CR Bard Inc, Murray Hill, NJ) is introduced over a stiffer wire and deployed at the distal landing site, ensuring a minimum 15 to 20 mm overlap with the helical side arm. Additional Fluency grafts can be used to extend the repair deeper into the main IIA trunk or, preferably if necessary, into the nonaneurysmal posterior IIA trunk (after embolization of the nontreated anterior trunk). The IBD is mated proximally to the aortic device using a leg extension modified with crimps to the distal fabric that interdigitate with crimps of the proximal H-IBD fabric, increasing the coefficient of friction and improving the pull-out force.

BB-IBD. This device resembles a bifurcate component used for fenestrated stent graft completion whose ipsilateral limb has a helical side arm branch attached in a similar manner as the H-IBD described above. This design obviates the need for leg extensions to join with an aortic body and is thus preferred in patients with shorter CIAs. Access from the contralateral side into the helical side arm is via a fenestration opposite and cranial to the branch ostium, which is later sealed by an overlaying segment of fabric and stent. A wire, preloaded through this self-sealing fenestration directly into the helical side arm, is snared from the contralateral groin and a 9 to 10F Flexor sheath (Cook Inc) is placed, allowing IIA access and stenting in a manner similar to the H-IBD. After IIA branch completion, removal of the sheath allows the fabric and stent overlying the self-sealing fenestration to close, preventing leakage. The BB-IBD mates proximally with a fenestrated/branched graft (or an aortic cuff for an infrarenal aneurysm) with the contralateral limb placed in standard fashion to complete the repair.

Follow-up. Patients were followed with computed tomography scans within 1 month, optionally at 6 months, then at 12 months, and annually thereafter. Duplex ultrasounds were also obtained for patients treated with fenestrated/branched devices. Endovascular results pertaining to reinterventions, sac morphology changes, and endoleaks were reported as per the endovascular reporting standards.[9,10] Technical success was defined as IBD device placement, cannulation, and a patent iliac branch without evidence of type I or III endoleak, in addition to survival for 24 hours. Severe IIA ostial stenosis was defined as a diameter reduction of >50% on centerline of flow measurement, and an IIA aneurysm was defined as >10 mm in diameter. A narrow CIA bifurcation was defined as a CIA diameter immediately proximal to the bifurcation of <16 mm, given that the device plus branch takes up 18 mm of space.

Statistics. Analyses were performed with SAS (v. 9.1; SAS Inc, Cary, NC) and R2.8 software (Vienna, Austria). Continuous data were compared using Student *t*-test. Patency and mortality were assessed using Kaplan-Meier life-table analyses and differences between groups were compared using the log-rank test and truncated when the standard error exceeded 10%. Correlation coefficients were calculated using the Spearman's rank correlation test. A *P* value of <.05 conferred statistical significance.

RESULTS

From October 2003 to February 2012, 138 helical branches were placed into 130 patients; 98 branches were H-IBD, while 40 were BB-IBD. Patient demographics and aneurysmal diameters are listed in (Table I). Mean H-IBD follow-up was 24.1 months (range, 1-72) and BB-IBD 7.7 months (range, 1-24) with an overall mean of 20.3 months.

The proximal component of the branched graft was connected to a fenestrated/branched endograft in 70 (51%) patients and an infrarenal graft in 63 (45%) patients. In five cases (4%), the IBD was docked into a limb of a previous aortic repair, with four sealing independently and one requiring a standard bridging leg extension graft (TFLE 12-37) for connection. Two cases of failed IIA access required the use of a leg extension (TFLE) to connect the IBD to the aortic mating device and cover the ostium of the helical branch (neither case required embolization of the IIA or developed an endoleak).

Table I. Patient demographics

Characteristics	*H-IBD total*	*BB-IBD total*
Total population	90	40
Age at repair, mean (SD)	71.3 (7.8)	71.4 (8.8)
Maximum aneurysm diameter, mean (SD)	60.7 (11.0)	59.1 (11.5)
Treated common iliac aneurysm diameter, mean (SD)	34.6 (12.1)	31.2 (9.9)
Treatment side internal iliac aneurysm (>10 mm)	31	13
Proximal extent of aneurysm		
Infrarenal	43	19
Suprarenal	47	21
Length of treated CIA, mean (range), mm	68 (25-110)	55 (15-108)
Family history of aneurysms	9 (13.1)	4 (10)
Male sex	83 (94.0)	39 (97.5)
Tobacco history	77 (85.5)	27 (67.5)
Hypertension	38 (42.2)	19 (47.5)
Coronary artery disease	43 (47.8)	23 (57.5)
Diabetes mellitus	22 (24.4)	9 (22.5)
Chronic renal insufficiency	14 (15.5)	5 (12.5)
Chronic obstructive pulmonary disease	22 (24.4)	9 (22.5)

BB-IBD, Bifurcated-bifurcated IBD; *CIA,* common iliac artery; *H-IBD,* helical-IBD; *IBD,* iliac branch device; *SD,* standard deviation.
This table depicts the demographics of the patients treated with an H-IBD vs a BB-IBD.
Data are presented as number (%) unless otherwise indicated.

Only 10 branches using the 6-mm limb were deployed (all prior to August 9, 2005). The most commonly used mating stent graft was the Fluency self-expanding stent graft (98%) (Fluency; CR Bard Inc), followed by the Viabahn (2%) (W. L. Gore, Flagstaff, Ariz). In H-IBDs, a balloon-expandable stent was deployed within the self-expanding stent graft sealing within the helical limb to ensure reinforcement up to the branch ostium in many cases (90%). This reinforcement was not necessary following the introduction of nitinol reinforcement rings along the branch in the H-IBD2. In BB-IBDs, additional reinforcement was required in 13 of 40 cases, most commonly when treating extreme anatomies.

Mortality. Thirty patients have expired following H-IBD or BB-IBD placement. All mortalities were H-IBD subjects, and only one was an aortic-related death. This subject had successful H-IBD implantation and an intact aneurysm repair but expired 6 hours postoperatively from an autopsy-proven myocardial infarction. For the entire IBD cohort, Kaplan-Meier calculations estimate a 30-day, 12-month, 3-year, and 5-year survival rate of 99%, 90%, 79%, and 62%, respectively (Fig 3). Survival stratified by proximal extent of disease (thoracoabdominal vs infrarenal) was similar (65% vs 60% at 5 years, respectively).

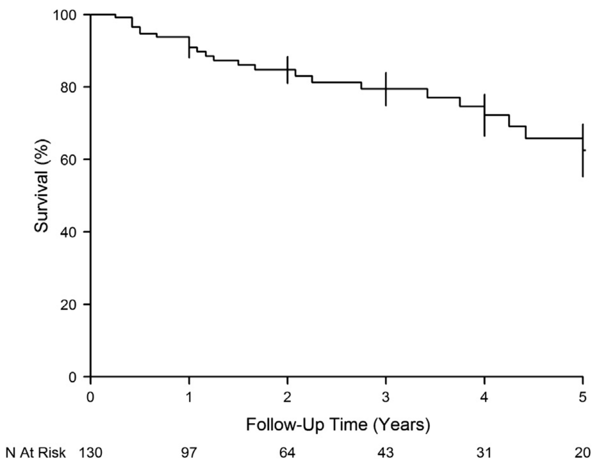

Fig 3. This Kaplan-Meier curve estimates the survival for all of the patients in the trial. Through 7 years, the standard error was under 10%.

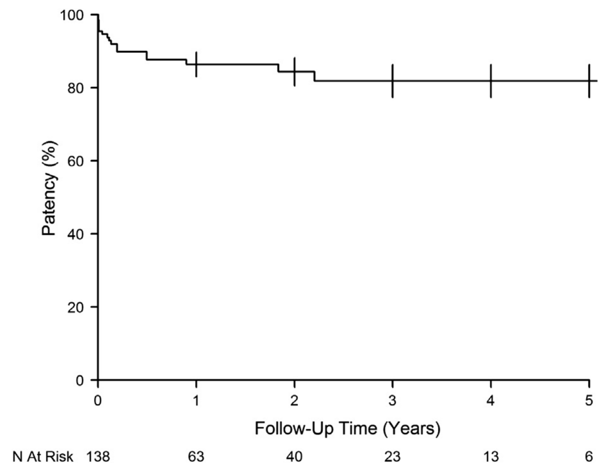

Fig 4. Branch patency for the entire cohort is demonstrated by the Kaplan-Meier curve in the figure. Standard error was <10% throughout.

Technical success and helical branch patency. Technical success was achieved in 94% of cases; there were nine technical failures. Eight involved the H-IBD, one a BB-IBD, and none involving the H-IBD2. The sole BB-IBD failure related to an inability to cannulate the IIA at the time of the procedure; the resultant type III endoleak was rectified successfully 3 days later with mating stent graft placement via an arm approach. Of the eight H-IBD technical failures, one was due to myocardial death as previously described, five from failed IIA cannulation, and two from IBD dislodgement during insertion of more proximal devices. In each of the latter seven cases, the helical branch orifice was covered with a limb extension, and the repairs extended into the EIA. No endoleaks resulted from these technical failures.

Patency. Estimated patency at 30 days, 12, 24, 48, and 60 months was 94.6%, 86.4%, 81.8%, 81.8%, and 81.8%, respectively (Fig 4). A total of 18 occlusions were noted, of which 11 (including the seven technical failures resulting in occlusion) occurred within 30 days of implantation. The seven late occlusions occurred between 1 and 26 months postimplantation; 71% of these patients developed unresolving hip claudication (Table II).

Endoleaks and secondary interventions. There were four patients with IBD-related endoleaks (two H-IBD and two BB- IBD), all in patients with IIA aneurysms requiring sealing within the IIA posterior trunk. All were successfully treated. Freedom from IBD-related endoleak was 96% at 5 years. There were 12 IBD-related secondary interventions: four involved endoleak treatment (listed above), one had embolization of a middle sacral artery through feeder vessels of the IBD side,[11] and four had thrombosed EIA limbs of the IBD (three were reopened with thrombolysis and supplemental self-expanding nitinol stents distally, and one required a femoral-femoral bypass). All have remained patent through follow-up. The remaining three reinterventions included the completion of a planned staged procedure, attempted recanalization of an occluded iliac branch, and stenting of a stenosis at a junction between a crimped limb and an H-IBD. No stent fractures or component separations of the IBD or mating stent grafts were noted on follow-up.

Morphologic outcomes. While difficult to separate sac behavior related to an IBD vs the primary aortic component, iliac aneurysmal sac regression was most commonly observed (79 of 118 [67%]), while the aneurysm sac remained stable in the remainder, with no cases of sac growth.

Common iliac artery length. Mean CIA length treated with the H-IBD was 66.5 mm (32 patients <50 mm) prior to 2008 and 71.0 mm after BB-IBD availability with none <50 mm. CIA length in BB-IBD was 54.9 mm (range, 15-108 mm). Because of the mating benefits of the BB-IBD device with fenestrated or branched components, the BB-IBD was used preferentially in the setting of longer CIA during such cases (Fen 56.9 mm vs non-Fen 49.5 mm).

Internal iliac artery aneurysm. Forty-five (45) of 138 helical branches were placed into IIA aneurysms (mean, 17.6 mm; range, 11-47 mm). To achieve an adequate landing zone, the helical branch was mated with stents extending into a divisional trunk of the IIA in 35 cases (34 posterior, one anterior). In the remaining 10, the distal aspect of the IIA main trunk was adequate for seal. These IIA aneurysm cases resulted in three of the nine technical failures and all four cases of IBD-related endoleaks. Despite an increase in the overall mating stent graft length required (100.2 mm [range, 61-160] vs 76.7 mm [range, 36-121]) and a smaller distal vessel diameter (6.05 mm [range, 4-9] vs 7.86 mm [range, 4-10]), the patency of branches landing within a divisional branch was similar to those sealing into the main IIA (Table III; 77.7% vs 83.1% at 60 months; log-rank test, $P = .75$).

IIA ostial stenosis. Five of nine technical failure patients had severe IIA ostial stenosis. The stenosis precluded IIA visualization following sheath placement in

Table II. Details of late occlusion (>30 days) of helical limbs, H-IBD, and BB-IBD

Details of failure/occlusion	*Months patent*	*Bilateral IIA occlusion upon helical limb occlusion*	*Ischemia related to occlusion*
Proximal branch compression (4 mm)	1	Yes	Nil
Proximal branch compression (2 mm)	2	No	Hip claudication
Proximal branch compression (4 mm)	2	No	Hip claudication
Proximal branch compression (4 mm) from extreme proximal IIA tortuosity	6	Yes	Hip claudication
Occlusion secondary to left hypobranch EIA limb occlusion	6	No	Nil
Extreme tortuosity in conjunction with a prolonged episode of hypotension induced by an unrelated GI bleed	22	No	Hip claudication
Retraction of distal graft into IIA An sac; no endoleak as thrombosed sac	26	Yes	Hip claudication

BB-IBD, Bifurcated-bifurcated IBD; *EIA,* external iliac artery; *GI,* gastrointestinal; *H-IBD,* helical-IBD; *IBD,* iliac branch device; *IIA,* internal iliac artery. All of the late occlusions with respect to timing and the development of ischemic symptoms are described here. Note the prevalence of the development of unresolving hip/buttock claudication ipsilateral to the occlusion (71% of patients), detected by the patient at the time of the branch occlusion.

Table III. The effect of anatomic factors on device failure

	IIA aneurysm			*Severe IIA ostial stenosis*			*Narrow CIA bifurcation*		
	Yes, % (n = 45)	*No, % (n = 93)*	P	*Yes, % (n = 27)*	*No, % (n = 111)*	P	*Yes, % (n = 74)*	*No, % (n = 64)*	P
Technical success[a]	93.3	93.5	1	81.5	96.4	.015	95.3	91.9	.5
Endoleak[a]	6.7	1.1	.1	0.0	3.6	1	0.0	5.4	.12
Branch patency[b]									
30 days	97.6	93.1		88.7	96.1		91.8	97.1	
12 months	87.4	85.8		81.0	87.7		83.6	88.9	
24 months	87.4	83.1		81.0	84.8		83.6	84.9	
48 months	77.7	83.1		81.0	81.5		83.6	80.2	
60 months	77.7	83.1	.75	81.0	81.5	.45	83.6	80.2	.59

CIA, Common iliac artery; *IIA,* internal iliac artery.
[a]Fisher exact test for technical failure and endoleak analysis.
[b]Log-rank test for branch patency.
The specific anatomic criteria that affects outcome following IBD placement is critical to patient selection and the development of new devices. This table highlights the three primary factors: concomitant IIA aneurysms (requiring sealing zones deep in the pelvis), severe IIA ostial stenosis (potentially precluding access and compressing mating stent grafts), and narrow distal CIA (preventing full expansion of the IBD) and how they influence technical success, endoleak, and patency. Of note, only the presence of a severe IIA stenosis adversely affected technical success. Patency and endoleaks were unaffected by any variable. Of note, we could not easily define tortuosity mathematically, so that was not measured.

two patients (resulting in aborted attempts to place the branch), an iatrogenic dissection in one patient, and in the remaining two patients was unrelated to the source of technical failure. Overall technical success was 81.5% in patients with severe ostial stenosis vs 96.4% in patients without ($P = .015$), and patency at 30 days, 12, 24, 48, and 60 months was 88.7%, 81.0%, 81.0%, 81.0%, and 81.0%, respectively (Table III; Fig 5). When compared with patients without ostial stenosis, the patency was similar (log-rank test, $P = .45$).

Narrow distal CIA arteries (<16 mm). An approximate minimal CIA diameter of 18 mm is optimal for full expansion of the device (8-mm branch and 12-mm EIA limb). Initial experience was therefore limited to distal diameters >18 mm, but over time, we became more aggressive with smaller distal CIA diameters using a modified implantation technique (described below). Sixty-four of 138 branches (46%) were deployed in CIA bifurcations with a diameter <16 mm (mean, 12.6 mm; range, 5-15 mm), and 74% of branches were placed in CIA with thrombus in the region of the IIA origin, yet these factors did not influence technical success (Table III; 95.3% vs 91.9%; $P = .5$) or patency. In such cases, after graft deployment, a kissing-balloon technique involving a 6- to 8-mm balloon within the helical branch origin (via the contralateral groin) and a 12-mm balloon within the EIA limb of the IBD (via the ipsilateral groin) was often used. The balloon within the helical branch was left inflated until the nose cone of the IBD delivery system had been withdrawn below the IIA ostium.

DISCUSSION

An IBD is likely the optimal means of endovascular exclusion of CIA and IIA aneurysms, aiding us to extend repairs from healthy arteries proximally to healthy arteries distally. This approach does not compromise the sealing zone within the CIA as snorkels, sandwiches, or bell-bottom techniques may.[8,12,13] The literature reports IBD technical success rates >90%, primary patency rates of between 74% and 100% and low endoleak rates at up to

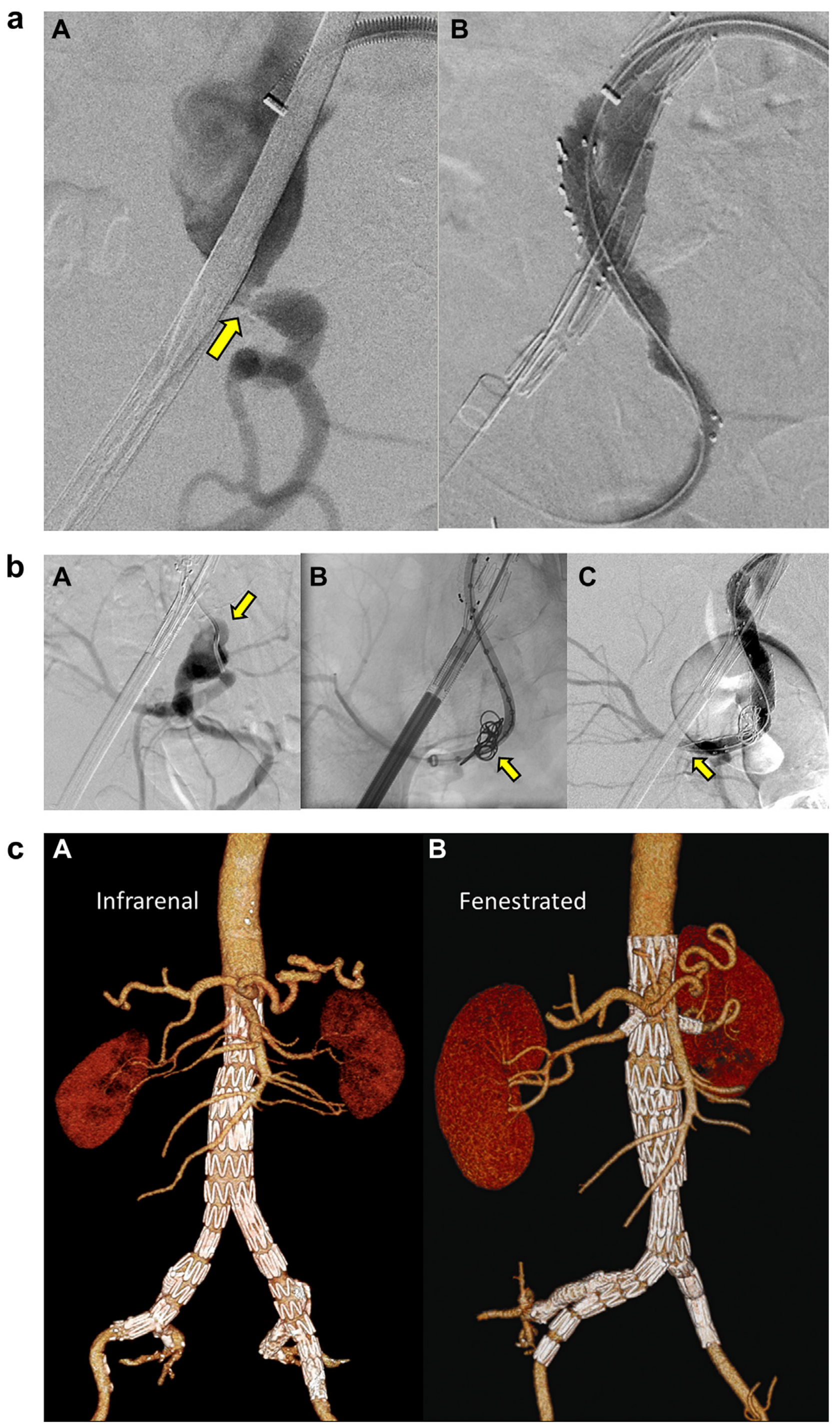

Fig 5. Intraoperative pictures. **a,** Tight ostial lesion **(A)** and stent graft in situ **(B)**. **b,** Internal iliac artery (IIA) aneurysm **(A)**, coiling of anterior divisional branch **(B)**, and placement of mating stent into the posterior divisional branch **(C)**. **c,** Completed repair: infrarenal device **(A)** and fenestrated proximal device **(B)**.

20 months follow-up[6,7,14,15] in anatomically carefully selected patients. Our results support the use of these devices, providing long-term follow-up with an evolved design in patients with few anatomic restrictions, in addition to analyzing morphologic details that may affect outcome.

It must be understood that patient comorbidities and anatomic factors may dissuade clinicians from treating all CIA/IIA aneurysms with IBDs. Although we emphasized strict physiologic exclusion principles (eg, overly sick patients, those unable to exercise to claudication), very

Table IV. Assessment of H-IBD patients for exclusion criteria for the PRESERVE-Zenith Iliac Branch System Clinical Study

PRESEVE national trial exclusion criteria	*No.*	*%*
CIA <50 mm	33	24
EIA diameter <8 mm	9	7
IIA >10 mm	45	33
Aortic bifurcation angle <40	15	11
CIA minimum diameter <16 mm	62	45
None	28	20
1	65	47
2	38	28
3	6	4
4	1	1

CIA, Common iliac artery; *EIA,* external iliac artery; *H-IBD,* helical-IBD; *IBD*, iliac branch device; *IIA,* internal iliac artery.
The Cook PRESERVE national trial utilizes the straight IBD device, initially with a mating balloon-expandable stent graft and then moving to a novel self-expanding stent graft made of Thoralon and Zilver stents. However, strict anatomic criteria were applied to allow patients to be enrolled in the trial. Our preoperative imaging data were reviewed for trial acceptability, and only 20% of the patients treated with IBD devices met all of the anatomic criteria for the trial. Estimates of anatomic acceptability based on other author's publications of less stringent anatomies are that 40% of the patients in this study would be candidates for other reports.

few patients were excluded for anatomic reasons. Patients with significant angulation, the need to seal deep within the IIA circulation, bilateral disease, and severe occlusive disease were all included in this series. The use of our current devices broadens the anatomic applicability for placement of these branched endografts. When the anatomic enrollment criteria, as outlined in published reports from iliac branched device feasibility studies, is applied to patients we have treated with the H-IBD/BB-IBD, only 20% of our treated patients would meet eligibility for the IBD U.S. national trial (Table IV); this is increased to 40% if enrollment criteria is based on enrollment criteria endorsed by others.[5,16] The combination of H-IBD/BB-IBD permits treatment of virtually all patients from an anatomic perspective, but we did not keep a log of the reason for rejection of a patient from the IBD study arms. This broadened applicability is critical in the setting of extensive aneurysms where IIA compromise risks spinal cord ischemia, as well as patients with bilateral disease where claudication appears more profound. Coupled with a limited number of device choices (a right- and left-sided device), the desire to use an IBD should not complicate the planning of endovascular procedures. These benefits are even more important when treating the Asian populations where the average CIA length is considerably shorter than in Caucasian patients (right CIA, 29.9 mm; left CIA, 34.2 mm),[17] which is optimally suited for the BB-IBD.

In patients with unilateral disease, the decision to occlude or preserve an IIA remains the subject of considerable debate. However, a significant number of patients will develop claudication if a single IIA is occluded,[18] as did 71% of our late occlusion patients. It is our belief that the claudication created by IIA loss is sustained and patients "learn" not to walk. Unfortunately, we cannot prove this point given that we only began routine treadmill testing (pre- and postoperatively and during follow-up studies) recently and, thus, have little long-term data. Yet, it stands to reason that if one elects to treat superficial femoral artery disease for claudication, why would one elect to cause claudication in aneurysm patients? Thus, clinicians will have to balance the potential for claudication (or other related complications) with the complexity, risk, and implant costs of adding an IBD to an aortic repair.

The devices are also intended to simplify deployment challenges in the setting of inherently tortuous anatomy. Device orientation within a tortuous iliac system straightened by stiff wires or delivery systems is difficult to predict, and accurate length measurements are hard to calculate when faced with the inherently tortuous nature of the IIA circulation due to ectasia, poststenotic dilations, and IIA aneurysms. Yet, the long overlap zone of the 27-mm helical branch allowed the use of only two mating devices for virtually all patients after 2005 (10-mm-diameter Fluency grafts, either 6 or 8 cm in length). The long overlap with the helical design allows one to focus almost entirely on the accuracy of stent graft deployment at the distal IIA landing zone, by providing flexibility with respect to the proximal overlap. Although the configuration of the Viabahn (W. L. Gore) was initially appealing, challenges were encountered with delivery and deployment accuracy in the setting of markedly tortuous situations, where the Fluency appeared to perform better with these designs. Furthermore, the helical design allows for smooth accommodation of the inherent angulation between the IIA and CIA in aneurysmal disease, resulting in little angulation within the completed branch (Fig 2). Perhaps this explains the high patency rates and absence of any fractures of the mating devices despite severe angulation.

The ability to treat challenging situations improved as we gained experience with the devices. In ostial IIA lesions, initial technical failures resulted from an inability to visualize the IIA after insertion of the device delivery system. Here, we modified our implantation technique by snaring the preloaded wire from the contralateral groin, withdrawing the delivery system caudal to the IIA origin, advancing an up-and-over sheath to allow cannulation and placement of a 6-mm balloon into the IIA origin via a second puncture in the sheath. The delivery system was re-advanced into position with the IIA balloon inflated. After IBD deployment, the balloon was removed leaving a wire marking the IIA origin, and a third sheath puncture allowed for introduction of a steerable catheter-guidewire combination to cannulate the IIA from within the branch. Similar improvements in our techniques were used in the treatment of IIA aneurysms. We generally preserved the posterior trunk of the IIA to avoid claudication. Here, after initial IBD deployment, the anterior IIA trunk was accessed through the sheath residing within the helical branch and coiled. The mating stent graft was subsequently placed into the posterior trunk obviating the need for staged embolization procedures, while providing additional stabilization for the embolization.

This series suffers from an absence of control patients or randomized cohort, precluding firm comparisons between IBD techniques and other methods of managing iliac pathology. Furthermore, the duration of follow-up varied, and we are unable to discuss results beyond 4 to 5 years with any significant numbers. Finally, there is a clear learning curve with IBD implantation, with greater experience improving our ability to treat more complex situations. The techniques learned were transferable to visceral and supra-aortic trunk branch procedures. It seems prudent to learn branch endografting techniques from IBD procedures (where occlusion generally results in claudication and endoleaks are easily treated by branch ostium coverage) rather than in other beds where the repercussions of failure are much greater. The actual proficiency of any given clinician with the implantation of IBDs is difficult to pinpoint. The required skill set largely revolves around endografting, but it also includes the ability to snare wires, deep IIA embolization techniques, and challenging ostial IIA cannulations in the setting of tight stenosis. Thus, most clinicians with experience in these areas will quickly learn how to employ IBDs in their practice, and others should take a more prudent approach, beginning only with relatively straightforward cases.

Overall, the two basic IBD configurations (H-IBDs and BB-IBDs) allowed for the treatment of essentially all patients with CIA/IIA aneurysms that had reasonable life expectancies and exercise abilities. The ability to preserve antegrade IIA flow in patients with TAAAs may aid in the prevention of spinal cord ischemia, whereas their application in less extensive aneurysmal situations will help to limit claudication and other more rare complications. Anatomic exclusions were decidedly uncommon, and the results in concomitant occlusive disease, IIA aneurysms, and narrow CIA diameters were akin to more favorable anatomies. The techniques and devices evolved over time and currently are considered by experienced interventionalists as adding little complexity to the endovascular repair of aortic aneurysms.

AUTHOR CONTRIBUTIONS

Conception and design: SW, RG
Analysis and interpretation: SW, RG
Data collection: SW, CB, JB
Writing the article: SW, RG
Critical revision of the article: RG
Final approval of the article: RG, TM, ME
Statistical analysis: TM
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